



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 29, 2020

Jennifer Reeder
Manager Regulatory Affairs
STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Vesta-Syde SQ 64 Ready-To-Use Disinfectant
EPA Registration Number: 1043-129
Application Date: 3/16/2020
Decision Number: 560858

Dear Ms. Reeder:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

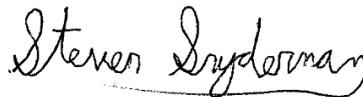
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup are large non-enveloped, and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline calicivirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

Vesta-Syde® SQ 64 Ready-To-Use Disinfectant

One-Step Disinfectant-Fungicide-Virucide*

EPA REG. NO. 1043-129

EPA Est. No. 1043-M0-2 - EPA Est. No. 11563-MI-1

FOR INDUSTRIAL AND INSTITUTIONAL USE

Active Ingredients:

Didecyl dimethyl ammonium chloride

0.159%

Isopropyl alcohol

10.000%

Other Ingredients:

89.841%

Total:

100.000%

KEEP OUT OF REACH OF CHILDREN
CAUTION

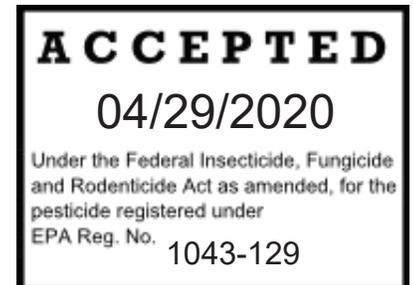
FIRST AID

In case of emergency, call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

IF ON SKIN OR CLOTHING: Call a poison control center or doctor for treatment advice. Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

REORDER NUMBER: () NET CONTENTS: ()

Manufactured by:
STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133
PRODUCT MADE IN THE U.S.A.



See (side panel) (back panel) (insert) for additional (precautionary statements) (directions for use).

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.



This ready-to-use product is intended for use on washable hard, non-porous environmental surfaces such as sealed floors, walls, counters, tools, carts, and other non-critical and semi non-critical medical equipment surfaces used in pharmaceutical and cosmetic manufacturing facilities, and in food processing, preparation and service facilities, in veterinary clinics and animal research facilities.

Use this product for cleaning and disinfection of hard, non-porous surfaces such as metal surfaces made of stainless or galvanized steel and chrome, glazed porcelain, plastics, glass, glazed tile, washable painted or varnished surfaces, sealed concrete, as well as resilient vinyl, linoleum, rubber or terrazzo.

DISINFECTANT: This ready-to-use product is effective in 10 minutes at 20°C on washable hard, non-porous surfaces, in the presence of 5% organic soil against the following: **Bacteria:** *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), *Staphylococcus epidermidis* (ATCC 12228), *Burkholderia cepacia* (ATCC 25416), *Enterobacter cloacae* (ATCC 13047), *Streptococcus pyogenes* (ATCC 19615), *Listeria monocytogenes* (ATCC 19111), *Micrococcus yunnanensis* (ATCC 7468), *Serratia marcescens* (ATCC 14756). **Fungi:** *Trichophyton interdigitale* (ATCC 9533), *Candida albicans* (ATCC 10231), *Aspergillus brasiliensis* (ATCC 16404) and *Aspergillus niger* (ATCC 6275). ***Viruses:** Influenza A2 Virus (A/2/Japan/305/57) (H2N2)*, Human Immunodeficiency Virus Type 1 (HIV-1)*, Avian Influenza (H9N2) Virus*, Human Rotavirus*, Strain: WA, ATCC VR-2018 and Feline calicivirus* (Surrogate for Human Norovirus), Strain: F9, ATCC VR-782.

ODOR CONTROL: This product eliminates many odors by killing odor-causing bacteria. Follow "**CLEANING AND DISINFECTING HARD, NON-POROUS SURFACES**" directions.

***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type HIV-1 (associated with AIDS).

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

CLEANING AND DISINFECTING HARD, NON-POROUS SURFACES:

Remove visible filth mechanically by sweeping or other appropriate cleaning techniques. Apply this ready-to-use product with a cloth, sponge, mop, brush, or coarse spray using normal cleaning methods. Thoroughly wet all surfaces to be cleaned. Treated surfaces must remain wet for 10

minutes. Then remove excess solution with a moist or damp applicator.

ANIMAL HUSBANDRY, ANIMAL RESEARCH, AND POULTRY FACILITY CLEANING AND DISINFECTING WASHABLE HARD NON-POROUS SURFACES: Remove all animals and feed from the premises, vehicles, and enclosures. Remove all litter and manure from the floors, walls, and surfaces of facilities traversed or occupied by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply product to hard, non-porous surfaces with a cloth, sponge, mop, brush, or coarse spray using normal cleaning methods. Saturate surfaces with product. Allow surfaces to remain visibly wet for 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate building, vehicles, and other closed spaces. Do not house livestock or empty equipment until treatment has absorbed, set, or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, and waterers with soap or detergent and rinse with potable water before reuse.

CLEANING AND DISINFECTING WASHABLE HARD NON-POROUS FOOD PREPARATION SURFACES AND PROCESSING FACILITIES AND EQUIPMENT: Cover or remove all food and packaging materials. Remove all visible soil. Thoroughly wet all hard, non-porous surfaces. Surface must remain wet for 10 minutes. Thoroughly rinse all wetted and cleaned surfaces with potable water.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) ON HARD, NON-POROUS SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application. Apply solution as directed in paragraphs above.

Contact Time: Allow surface to remain wet for 10 minutes.

Infectious Materials Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

STORAGE AND DISPOSAL

Do not contaminate food, feed or water by storage or disposal.

Pesticide Storage: Store in original container in a cool, well-ventilated area. Do not store near heat or open flame. If frozen, thaw and remix before use.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

(For < 5 gal.) Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents and dispose of as pesticide waste. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as pesticide waste. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(For > 5 gal.) Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents and dispose of as pesticide waste. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip

it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as pesticide waste. Repeat this procedure two more times.

*Optional Label Text is enclosed in parentheses.
(STERILE UNLESS PACKAGING IS COMPROMISED)*

Emerging Viral Pathogens Claims

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Feline calicivirus
Large, non-enveloped virus	Feline calicivirus

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against Feline calicivirus on hard non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Feline calicivirus on hard non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.”